IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC., UCB PHARMA GMBH, and LTS LOHMANN THERAPIE-SYSTEME AG,	)	
Plaintiffs,	)	Civil Action No. 19-474 (KAJ)
	)	**FILED UNDER SEAL**
v.	)	
ACTAVIS LABORATORIES UT, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION

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Wilmington, Delaware

JORDAN, Circuit Judge, sitting by designation.

I. INTRODUCTION

Defendant Actavis has filed a motion to exclude the expert testimony of Dr. Rahul Guha under Federal Rule of Evidence 702. (D.I. 103.) Specifically, that motion seeks to exclude Dr. Guha's testimony regarding the commercial success of the reformulated Neupro® product, which embodies claims of U.S. Patent No. 10,130,589 (the "'589 Patent"), the patent asserted by the plaintiffs (referred to collectively in the singular as "UCB"). Briefing on this motion was completed on September 1, 2020. For the reasons discussed below, I will deny Actavis's motion to exclude the expert opinion.

II. BACKGROUND

UCB filed this action on March 6, 2019, alleging that the rotigotine transdermal product Actavis wants to market pursuant to ANDA No. 206348 would infringe the '589 Patent. This Court, with Chief Judge Stark presiding, previously tried a suit between the same parties regarding related patents, U.S. Patent Nos. 6,884,434 (the "'434 Patent") and 8,232,414 (the "'414 Patent"), and held the '414 Patent invalid and the '434 Patent valid and infringed by Actavis's plan to market a generic version of the Neupro® product. *See UCB, Inc. v. Watson Labs., Inc.*, C.A. No. 14-1083 (LPS) (SRF) ("*UCB I*"). The '434 Patent is set to expire in the first quarter of 2021.

The Neupro® patch is approved by the FDA to treat Parkinson's disease and primary Restless Leg Syndrome. UCB states that, due to "a stability issue caused by crystallization of the rotigotine," it only marketed the original Neupro® patch from 2007

to 2008.[1] (D.I. 110 at 3.) According to UCB, that issue was "solved" by the '589 Patent, permitting the launch of the reformulated Neupro® product in 2012. Again according to UCB, the inventors of the '589 Patent discovered that the "narrow, claimed range of rotigotine:PVP ratios of about 9:4 to about 9:6 – stabilized the active rotigotine drug but did not adversely affect release rate of the drug from the transdermal patch, both of which are critical to making an effective [transdermal therapeutic system ("TTS"), or colloquially, patch] for treatment of Parkinson's disease, [which] was surprising and critical to allowing Neupro® TTS to return to the U.S. market." (D.I. 110 at 4.)

Following claim construction in the present suit, Actavis stipulated that its planned (reformulated) generic product would infringe the asserted claims of the '589 Patent, leaving the three-day bench trial set in this case to focus exclusively on invalidity. In support of the '589 Patent's validity, UCB has put forward testimony from Dr. Guha asserting that the reformulated Neupro® patch experienced commercial success, one of the secondary indicia of non-obviousness. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966) (describing "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc.").

Additionally, Dr. Guha "reviewed [UCB's] Orange Book patents related to Neupro® to determine whether any of them were 'blocking patents[,]'" which is legally related to the significance of commercial success.[2] (D.I. 110 at 4.) Actavis summarizes

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[1] The parties did not provide significant argument on the nature of the stability issues or their resolution.

[2] As will be discussed below, blocking patents cover the same or similar

what it believes to be Dr. Guha's excludable testimony as follows: first, despite being a late entrant into a crowded market, Neupro® experienced commercial success following its 2012 relaunch; second, given the criticality of the reformulation, "a nexus existed between the inventions claimed in the '589 Patent and Neupro®'s commercial success"; third, the commercial success is not attributable to excessive marketing; and fourth, UCB's other patents did not function as blocking patents. (D.I. 110 at 4-5.)

Actavis argues that Dr. Guha's testimony should be excluded because his methodology was unreliable and he failed to conduct a complete analysis.

III. LEGAL STANDARDS

The admissibility of expert testimony is governed by Federal Rule of Evidence 702. Under that rule, expert testimony is admissible only if it "will help the trier of fact to understand the evidence[,] ... is based on sufficient facts or data[,] ... is the product of reliable principles and methods[,] and ... reliably applie[s] the principles and methods to the facts of the case." Fed. R. Evid. 702. The role of the district court is to serve as a "gatekeeper"—to protect the fact-finder from evidence that is unreliable, confusing, or unduly prejudicial. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 145, 147–48 (1999); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589–92 (1993). There must, in that regard, be both reliable methodology in the analysis and an adequate "fit" between the proffered opinion and the facts at issue. *Daubert*, 509 U.S. at 591 (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985)). Expert conclusions that

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technology as a patent-at-issue and prevent or discourage research or investment by competition.

do not have an adequate analytical connection to the facts are excludable. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."). "*Daubert* considerations[,]" however, "are less pressing in the context of a bench trial." *LG Display Co. v. AU Optronics Corp.*, 265 F.R.D. 199, 202 (D. Del. 2010).

Pursuant to Federal Rule of Evidence 104, the burden of proof with respect to fit and reliability under Rule 702 lies with the party proffering the expert evidence. *See* Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("[T]he admissibility of all expert testimony is governed by the principles of Rule 104(a). Under that Rule, the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence.").

IV. MOTION TO EXCLUDE EXPERT TESTIMONY

Actavis argues that Dr. Guha's methodology was flawed and his analysis incomplete, resulting in opinions that cannot properly be put in evidence. Its first argument (*infra* Section IV.A) is premised on the principle that "the driver of commercial success [must be] 'what is both claimed and novel' in the patent-in-suit, 'as distinct from the prior art.'" (D.I. 104 at 2 (quoting *In re Huai-Kung Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011); Higgins Decl., Ex. 1, Dep. Tr. of Rahul Guha ("Guha Dep. Tr.") 97:4–9).) UCB does not contest Actavis's statement of law but argues instead that it was appropriate for Dr. Guha, relying on representations from UCB's counsel and technical experts, to tie commercial success to the claimed invention without naming the novel elements of the invention. (D.I. 110 at 6-13.) UCB asserts it will be the province of

technical experts to opine on which aspects of the invention are novel, while the job of the economic expert is to tie commercial success to the claimed invention, and the role of the Court is to assess the effectiveness of the commercial success argument based on this combination of testimony.

Actavis also challenges Dr. Guha's testimony as to blocking patents (*infra* Section IV.B), arguing that he did not analyze the universe of patents that could be blocking patents. UCB says that Dr. Guha conducted a proper analysis of blocking patents and that Actavis's criticism about unconsidered patents is properly the subject of cross examination.

At this stage, I agree with UCB on both issues.

A. Testimony on Commercial Success

"Obviousness is a question of law based on underlying factual determinations including: (1) the level of ordinary skill in the pertinent art, (2) the scope and content of the prior art, (3) the differences between the prior art and the claims at issue, and (4) secondary considerations of non-obviousness such as commercial success, long-felt but unsolved needs, failure of others, etc." *Novartis Pharm. Corp. v. W.-Ward Pharm. Int'l Ltd.*, 923 F.3d 1051, 1059 (Fed. Cir. 2019) (quoting *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007)) (internal quotation marks omitted). "For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the *claimed invention*." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (brackets omitted); *see Novartis AG v. Torrent Pharm. Ltd.*, 853 F.3d 1316, 1330 (Fed. Cir. 2017) (quoting same); *In re Huai-*

Kung Kao, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (quoting same). Economic testimony need not, however, pre-establish a nexus to the merit of the invention in order to be admissible. For admissibility, it is enough for the opinion to show a nexus will be established by other competent evidence. *See Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1350 (Fed. Cir. 2012) (synthesizing trial testimony from Transocean's damages expert and various witnesses to reverse the district court's grant of JMOL and find "sufficient evidence of both commercial success and nexus to the features of the claimed invention"); *Cf. WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016) ("We further reject Kohler's categorical claim that objective evidence must be tied exclusively to claim elements that are not disclosed in a particular prior art reference in order for that evidence to carry substantial weight.").

Actavis acknowledges that "Dr. Guha opines that there is nexus between the Claimed Inventions and Neupro®'s commercial success[,]" but contends that he should have conducted "an independent determination of the merits or novelty" and identified "what those features were." (D.I. 104 at 8 (citation and quotation marks omitted).) Moreover, Actavis alleges that Dr. Guha inappropriately relied on information from UCB's counsel to assume "that all sales can be attributed to the claimed invention of the '589 Patent." (D.I. 104 at 8.) But, as UCB correctly notes, it is not Dr. Guha's role to conduct a technical analysis, and he is within his prerogative as an economic expert to rely on the representations of counsel and technical experts as to the technical aspects of the Patent. *See Apple, Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1321 (Fed. Cir. 2014) ("Experts routinely rely upon other experts hired by the party they represent for expertise

outside of their field."). On this record, any issues relating to Dr. Guha's methodology or the credibility of the information he relies upon can be adequately addressed through cross-examination.

Actavis further contends that Dr. Guha "failed to consider in his analysis of commercial success the other patents listed in the Orange Book as covering Neupro®" and was unaware of certain patents "cover[ing] rotigotine-containing transdermal patches." (D.I. 104 at 9.) According to Actavis, these should have been analyzed to understand if commercial success emanated from an invention other than the '589 Patent, and failure to consider these makes his testimony unreliable. But Dr. Guha claims to have reviewed UCB's Orange Book patents covering Neupro®, and the weakness Actavis says exists in his proposed testimony can be adequately addressed through cross examination. The same is true of Actavis's contention that Dr. Guha failed to apportion sales between unique and non-unique features of the patented product.

Actavis adds that Dr. Guha did not review this Court's decision in *UCB I*, which found a nexus between long-felt but unmet need and the '434 Patent, and notes that the Court stated, "Neupro was the first and only transdermal patch available to treat Parkinson's disease." (Higgins Decl., Ex. 7, *UCB I* Memorandum Opinion ("*UCB I* Opinion") at 72.) Once again, that is a basis for cross-examination. Similarly, what Actavis says is Dr. Guha's failure to "exclude sales that are attributable to features found in the prior art[,]" and its assertion that the prior art is the basis of the product's commercial success (D.I. 104 at 13), are matters of dispute that Actavis will have an opportunity to address at trial.

UCB has adequately shown that Dr. Guha tied – using his economic expertise – features of the claimed invention with evidence of commercial success for purposes of admissibility. *See Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1304 (Fed. Cir. 2010). Actavis freely admits that Dr. Guha identified certain features driving success but contends that those features "were known in the prior art and previously asserted by UCB as being related to the '434 Patent, both of which Dr. Guha failed to consider." (D.I. 104 at 12.) Those are arguments it can make at trial.

B. Testimony on Blocking Patents

Actavis also argues that Dr. Guha's testimony regarding the lack of blocking patents should be excluded "due to his utter disregard of the full scope of the 'blocking patent' analysis."[3] (D.I. 104 14.) Dr. Guha's testimony on the lack of blocking patents is significant to his overall testimony on commercial success because the Federal Circuit has held that, where blocking patents exist, "the inference of non-obviousness of [the asserted claims,]" based on "evidence of commercial success, is weak." *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2017) (quoting *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005)).

The basis for Actavis alleging methodological failure is its contention that Dr. Guha failed to "look[] at the entirety of [UCB's] portfolio of patents covering transdermal patches in coming to [his] opinions." (D.I. 104 at 15 (quoting Guha Dep. Tr.

[3] "A patent [is] called a 'blocking patent' where practice of a later invention would infringe the earlier patent." *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1337 (Fed. Cir. 2018). Such patents discourage competition or investment in like technology.

126:14–127:4).) Actavis claims this means Dr. Guha relied on insufficient facts to form an opinion on the existence of blocking patents. UCB answers that Dr. Guha "considered all of [UCB's] Orange Book patents for Neupro®," which includes "about a half a dozen." (D.I. 110 at 14.) UCB continues that, at deposition, and in the briefing on this motion, Actavis "failed to offer to Dr. Guha any patent belonging to [UCB] that could be considered a 'blocking patent' that he had not reviewed in preparing his report." (D.I. 110 at 14.) Actavis may have named one patent application that never issued as a patent, but UCB insists that "Dr. Guha considered all of the relevant patents of [UCB's] in conducting his 'blocking patent' analysis." (D.I. 110 at 15.) I agree with UCB that this is an issue for trial.

V. CONCLUSION

For the foregoing reasons, I will deny Actavis's motion to exclude the expert testimony and opinion of Dr. Rahul Guha.